STATE MEDICAID DUR BOARD MEETING

THURSDAY, May 10, 2007
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:
Don Hawley, DDS.
Karen Gunning, PharmD.
Lowry Bushnell, M.D.
Mark Balk, PharmD.
Jeff Jones, R.Ph.
Colin VanOrman, M.D.

Board Members Excused:
Derek Christensen, R.Ph.
Bradford Hare, M.D.
Joseph Miner, M.D.
Dominic DeRose, R.Ph.
Wilhelm Lehmann, M.D.
Bradley Pace, PA-C

Dept. of Health/Div. of Health Care Financing Staff Present:
Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Richard Sorenson, R.N.
Lisa Hulbert
Suzanne Allgaier, R.N.
Merelynn Berrett, R.N.
Nanette Epstein
Duane Parke, R.Ph.

Other Individuals Present:
Craig Boody, Lilly
Karen Bowyn, AstraZeneca
Jen Kammerer, AstraZeneca
John Stockton, Genentech
Alan Bailey, Pfizer
Oscar Fuller, CMS
Jeff Buell, Johnson & Johnson
Tim Smith, Pfizer
Nancy Fairchild, Sepracor
Robb Host, Cephalon
Sabrina Aery, BMS
Tom Hold, Schering-Plough
Brett Brewce, EMD Serono
Jay Jennings, Sanofi-Aventis
Barbara Boner, Novartis
Gordon Tattersall, Pfizer
David Stallard, AG
Brad Carter, King
Jerry Gomez, King Pharma
Sara Pierer Hardy
James Gaustad, Purdue
Matt Johnson, Takeda
Reed Murdock, Wyeth

Meeting conducted by: Lowry Bushnell

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1. Minutes for April 12, 2007 were reviewed, corrected and approved.

2. Housekeeping: Dr. Bushnell has completed his term as Chairman of the DUR Board. The

Board thanked him for his service. Election of a new Board Chairman was postponed due to low attendance at this meeting.

3. PDL Discussion: Duane Parke addressed the Board. The current scheduled PDL implementation date is August 1, 2007. The first two classes that will be implemented on the PDL have already been approved by the DUR Board. A P&T Committee cannot yet make recommendations about preferred agents, since the Department has not yet received sufficient nominations to be able to seat a P&T Committee. The Board was asked to choose preferred agents for the PDL for the two classes - PPI's and high-potency Statins. Non-preferred drugs will require "Dispense as Written - Medically Necessary" to be written on the prescription. The Department does not yet have secondary rebate information to be able to determine cost of all of the agents in these two classes, so it is suggested that the Board look at the least expensive agents in each class. High-potency Statins that are least costly are Vytorin and Crestor, and PPI's that are least costly are Prilosec OTC, Prevacid and Protonix.

   The Board wanted to know why they were being asked to make this decision. The Department stated that this is due to the lack of a P&T Committee.

   Karen Gunning stated that she is concerned about making a decision based on cost alone. There may not be great differences in PPI's, but there are other relevant considerations among the Statins besides the cost. Specialized physicians will be invited to the P&T Committee to provide advice on the drug classes under discussion. Also, members will have the opportunity to further research drug classes being discussed in a P&T Committee meeting prior to making a recommendation.

   The Board felt that it was inappropriate to make a recommendation in the DUR Board meeting at this time, and wanted to defer discussion of this issue until the P&T Committee has a chance to meet and make recommendations to the DUR Board.

   The Board asked if the cost information that is provided is based on current prices that the Department is paying, or if the prices will be negotiated. The Department stated that this depends on whether or not Utah will be able to join a purchasing pool. If Utah joins a purchasing pool, discussions about cost will be made in private sessions of the P&T Committee meetings, since the secondary rebate information is proprietary.

   The Department would like to bring back recommendations for preferred agents next month, due to the time constraints involved in the August 1 implementation date. The Department has a 90-day window for education and notice when changes are made in policy.

   A motion was made to devote the entire June DUR meeting to discussion of the PPI's and Statins. Concern was raised that public comment may become excessive in a DUR Board meeting. Concern was also raised that the P&T Committee may have different findings and recommendations than the DUR Board, and create confusion for clients and providers.

   The Department acknowledged that the time constraints surrounding implementation have created an unfavorable situation. Tim Morley suggested that the Department could request more time to implement the PDL. Karen Gunning offered to speak with people at the Department to explain the difficulties surrounding the implementation timeframe. Dr. Bushnell suggested that the DUR Board could approve all agents in a particular group as preferred drugs to meet the time requirements requested by the Legislature until a P&T

Committee can be formed and take appropriate action. RaeDell Ashley suggested that the Attorney General can come and explain to the DUR Board what they are required to do under the law.

A new motion was made that the DUR Board look only at the PPI's during the next meeting. The motion was passed. The Board also requested that the Attorney General come and speak at a future meeting to provide clarification about the law, and so that the Board can explain why they must take care throughout the PDL process.

The Board was given a list of the top twelve drug classes by cost for Medicaid. Atypical antipsychotics were the top class by cost, and Abilify alone was number five or six on the list. These two drug classes are, by law, exempt from a PDL. However, the list may, in general, be a good tool to use for considering future classes of drugs for the PDL.

The Board asked how the P&T Committee will determine what drug classes to consider for a PDL. The P&T Committee and DUR Board will share a dynamic relationship. The DUR Board may provide direction to the P&T Committee on which drug classes should be reviewed. The P&T Committee may also select a drug class for review on its own, and make a recommendation to the DUR Board.

4. Anti-Psychotic ICD.9 Review: Tim Morley addressed the Board. Several years ago, the Board took action with regard to controlling the appropriate utilization of antipsychotics. The Board chose to do that by approving a list of ICD.9 codes for which Medicaid would be authorized to pay. The ICD.9 code would need to be placed on the prescription by the physician at the time that the prescription was written. Recently, there has been a lot of controversy with regards to off label prescribing and off label marketing of antipsychotics. The State has made some inquiries with regards to whether or not Medicaid is following prudent practice with such a large list of ICD.9 codes when the atypical antipsychotics are only approved for a limited amount of indications - schizophrenia and bipolar disorder. There are a number of variations on these two diagnoses for which a rational argument could be made as to whether or not atypical antipsychotics should be covered. The Board was provided with a packet of all of the currently approved ICD.9 codes with notes indicating whether or not the indications are FDA approved or listed in the approved compendia. The shaded indications are nether FDA approved nor listed in the compendia, so by statute and by OBRA Law they should not be paid. The provided list also breaks out whether or not the indication is approved for the given age.

Dr. Bushnell stated that the Board had essentially approved this list provided by the mental health community some years ago. The mental health community had felt strongly about including the diagnoses that they felt would be needed and provided the Board with a list that they felt should be included. Dr. Bushnell suggested that Medicaid meet with Dr. Yau of Valley Mental Health and whomever else he recommends from the mental health community to re-evaluate what diagnoses really need to be included on the list.

Karen Gunning stated that she would like to see what people are actually using the atypical antipsychotics for. If there are significant areas with utilization that are non-approved, that builds a basis for discussion with prescribers about how the drugs are being used. Medicaid provided this list.

The Board raised some concern that these codes may be put on at the pharmacy, rather than

by the prescriber. Karen Gunning recommended that Medicaid provide The Board with a recent document published by the AHRQ on the efficacy of comparative effectiveness of off-label use of atypicals. It is a fairly short document that provides valuable information looking at key points about where there is information about off-label usage habits. Any decision should be made in context with the mental health community.

Medicaid did not expect that the Board would be able to come to any consensus during this meeting, but wanted to initiate the discussion with the Board since the State has some concerns. There is also pending litigation against drug manufacturers and prescribers due to the side-effects associated with these drugs for off-label indications for these drugs.

The Board asked Medicaid to discuss the issue with mental health providers to determine what indications are really needed. It would be beneficial to bring it to the Board after the mental health community has been able to provide input behind closed doors.

Medicaid informed the Board that the Attorney General's office is currently doing an analysis to determine if the DUR Board has the authority to approve lists of ICD.9 codes as they had done with the initial ICD.9 list.

5. Tekturna: Tim Morley addressed the Board. Barbara Boner of Novartis was asked if anyone from Novartis would like to address the Board regarding Tekturna. There was no one from Novartis who wanted to address the Board, but Barbara Boner made herself available to answer any questions that the Board has.

This is a new class of drugs that acts on the renin-angiotensin-aldosterone system. Tekturna acts in this cycle. It shares some of the same side-effects of other drugs that act on this system. It is a direct renin inhibitor, and steps in between all of the feedback loops that create problems with ACE inhibitors or ARB's.

The Board found this drug difficult to place based on the available studies. There are some patient populations that this drug has not been studied in and some drug classes that this drug has not been studied with, and conditions for which the drug has not been studied, but is not appropriate for step therapy. However, there are doses above which the drug does not appear to offer added benefit while increasing the side effects. A motion was made to limit the monthly quantity that Medicaid will cover to 30 per month of either strength.

The Board asked if a 30 per month limit would create problems with titration. Medicaid can authorize an override in the event of a dosage change.

The Board approved a cumulative quantity limit of 30 per month for both strengths of Tekturna.

6. Vivitrol: Tim Morley addressed the Board. Vivitrol is a reformulation of Naltrexone in a long-acting injectable suspension. The dose is 380mg IM once monthly. It has been out since about July, but no claims for this drug have been found in the Data Warehouse. It is indicated for the treatment of alcohol abuse, and, because it also has applications in other areas, Medicaid needs to manage how it is used. This drug will circumvent problems with oral dosage forms, since a patient cannot fake taking the drug.

The Board asked if this is an office-administered drug. It is for use in a physician's office

and will be billed by Jcode.

The Board also asked if this is a depo form. It is a depo injection that lasts one month.

There are some strict guidelines in the manufacturer's instructions. It must be used only for alcohol abuse, the patient must have a negative opioid screen or pass a naloxone challenge. There needs to be some psychosocial support involved in the patient treatment. The Board also pointed out that patients on this drug should wear metal bracelets indicating that they are receiving this drug in the event that they end up needing emergency treatment involving opioids.

The Board asked if any consideration should be given to the Black Box Warning regarding liver problems. Medicaid can add liver function tests to the PA requirement. The manufacturer pointed out that the studies leading up to the Black Box Warning used in excess of 5 times the dose that will be administered by the physician. Medicaid asked the manufacturer to clarify the dosages that were used in these studies. The studies that were conducted with higher doses involved very obese patients and were meant to determine what the appropriate doses of naltrexone were for these patients. At 5 to 6 times the recommended dose, the patients that were in the study began to show signs of liver disease. These studies involved naltrexone, but not necessarily Vivitrol. With regards to pain management, patients are given an ID bracelet to indicate that they are receiving naltrexone.

The Board asked the manufacturer about the appropriate duration of treatment. Most of the patients enrolled in the study received therapy for 6 months. Some patients were enrolled in extensions out to 18 months. There are no limits on how long a patient could receive therapy with Vivitrol, and the decision to continue beyond 18 months can be left to the patient and physician. Studies essentially indicate that at 18 months patients do not appear to develop tolerance and go back to drinking. The FDA did not give any limits for length of time on the therapy.

Medicaid asked the Board for a recommendation for a time limit on Vivitrol similar to the smoking cessation products that have limits on them. The Board asked where most of the patients enrolled in Medicaid receive treatment for alcohol dependance. There are a number of programs in the Valley that accept Medicaid clients. These include Valley Mental Health and the University of Utah. Medicaid recommended that the Board consider a six month maximum prior approval.

The Board considered the criteria proposed by Medicaid with the addition of liver function tests and a six month renewable time limit on the prior authorization. The Board approved these criteria.

Next meeting set for May 14, 2007
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered four petitions.